

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF NEW YORK

**JEANINE A. SORTISIO and STEVEN R.  
SORTISIO,**

**Plaintiffs,**

**v.**

**PETER ACCETTA, M.D., SUSAN M.  
PETERSON, RPA-C, ASTELLAS PHARMA  
US, INC., and NOVARTIS  
PHARMACEUTICALS CORPORATION,**

**Defendants.**

**Civil Action No.:** 1:09-CV-00176-RJA

*Document electronically filed.*

**ANSWER OF DEFENDANT  
ASTELLAS PHARMA US, INC.**

**JURY TRIAL DEMANDED**

Defendant Astellas Pharma US, Inc. ("APUS"), by and through its counsel, submits the following Answer to Plaintiffs' Complaint ("the Complaint"):

1. APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 1 of the Complaint, and, therefore, denies the same.

2. The allegations set forth in Paragraph No. 2 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 2 of the Complaint and, therefore, denies the same.

3. The allegations set forth in Paragraph No. 3 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a

belief as to the truth of the allegations set forth in Paragraph No. 3 of the Complaint and, therefore, denies the same.

4. The allegations set forth in Paragraph No. 4 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 4 of the Complaint and, therefore, denies the same.

5. The allegations set forth in Paragraph No. 5 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 5 of the Complaint and, therefore, denies the same.

6. The allegations set forth in Paragraph No. 6 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 6 of the Complaint and, therefore, denies the same.

7. The allegations set forth in Paragraph No. 7 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 7 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

8. The allegations set forth in Paragraph No. 8 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 8 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

9. APUS admits, based on information and belief, that the amount in controversy satisfies the jurisdictional requirement of this Court. APUS denies any remaining allegations in Paragraph No. 9 of the Complaint.

**In Response to “As and For a Second Cause of Action”**

10. With respect to Paragraph No. 10 of the Complaint, APUS repeats and incorporates by reference its responses set forth in Paragraph Nos. 1-9 as if fully set forth herein.

11. The allegations set forth in Paragraph No. 11 of the Complaint are directed at defendants other than APUS and, therefore, no response is required. To the extent a response is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 11 of the Complaint and, therefore, denies the same.

12. APUS states that, since April 1, 2005, it has been duly authorized to conduct business in New York, and has distributed, marketed, and sold prescription medications for use upon prescription only through licensed physicians in New York in accordance with its FDA-approved prescribing information and subject to the precautions, warnings, contraindications, and other information contained therein. APUS denies any remaining allegation in Paragraph No. 12 of the Complaint.

13. APUS denies all allegations set forth in Paragraph No. 13 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 13 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 13 of the Complaint and, therefore, denies the same.

14. APUS denies all allegations set forth in Paragraph No. 14 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 14 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 14 of the Complaint and, therefore, denies the same.

15. APUS denies all allegations set forth in Paragraph No. 15 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 15 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 15 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Elidel and/or Protopic® have defects or inherently dangerous propensities.

16. APUS denies the allegations set forth in Paragraph No. 16 of the Complaint.

17. APUS denies all allegations set forth in Paragraph No. 17 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 17 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to

these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 17 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

**In Response to “As and For a Third Cause of Action”**

18. With respect to Paragraph No. 18 of the Complaint, APUS repeats and incorporates by reference its responses set forth in Paragraph Nos. 1-17 as if fully set forth herein.

19. APUS denies all allegations set forth in Paragraph No. 19 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 19 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 19 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

20. APUS denies all allegations set forth in Paragraph No. 20 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 20 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 20 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

21. APUS denies all allegations set forth in Paragraph No. 21 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 21 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 21 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

**In Response to “As and For a Fourth Cause of Action”**

22. With respect to Paragraph No. 22 of the Complaint, APUS repeats and incorporates by reference its responses set forth in Paragraph Nos. 1-21 as if fully set forth herein.

23. APUS denies all allegations set forth in Paragraph No. 23 of the Complaint that are directed at APUS. The remaining allegations set forth in Paragraph No. 23 are directed at defendants other than APUS and, therefore, no response is required. To the extent a response to these allegations is deemed necessary, APUS states that it is without knowledge or information sufficient to form a belief as to the truth of these allegations set forth in Paragraph No. 23 of the Complaint and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

24. APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 24 of the Complaint, and, therefore, denies the same.

25. APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 25 of the Complaint, and, therefore,

denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

26. The allegations set forth in Paragraph No. 26 of the Complaint constitute legal conclusions, and, therefore, no response is required. To the extent a response is deemed necessary, APUS denies the allegations set forth in Paragraph No. 26 of the Complaint.

**In Response to “As and For Fifth Cause of Action”**

27. With respect to Paragraph No. 27 of the Complaint, APUS repeats and incorporates by reference its responses set forth in Paragraph Nos. 1-26 as if fully set forth herein.

28. APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 28 of the Complaint, and, therefore, denies the same.

29. APUS states that it is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph No. 29 of the Complaint, and, therefore, denies the same. Further answering, APUS specifically denies that Jeanine Sortisio was injured as a result of her alleged use of Elidel and/or Protopic®.

APUS admits that Plaintiffs seek the relief stated in the WHEREFORE paragraph following Paragraph No. 29 of the Complaint, but denies that Plaintiffs are entitled to such relief.

**GENERAL DENIAL**

APUS denies all allegations and/or legal conclusions in the Complaint that have not been previously specifically admitted, denied or explained.

**AFFIRMATIVE AND OTHER DEFENSES**

APUS reserves the right to rely upon any of the following or additional defenses to claims asserted by Plaintiffs to the extent that such defenses are supported by information developed through discovery or by evidence at trial.

**FIRST AFFIRMATIVE DEFENSE**

30. Upon information and belief, Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**

31. Upon information and belief, any purported injuries of which Plaintiffs complain in the Complaint were not caused by APUS, but were caused by the actions or inactions of a person or persons or entities over whom APUS had neither control nor right of control.

**THIRD AFFIRMATIVE DEFENSE**

32. Upon information and belief, the claims asserted by Plaintiffs are barred by the applicable statute or statutes of limitations and/or repose.

**FOURTH AFFIRMATIVE DEFENSE**

33. APUS has no legal relationship or privity with Plaintiffs and owes no duty to Plaintiffs by which liability can be attributed to it.

**FIFTH AFFIRMATIVE DEFENSE**

34. Upon information and belief, APUS made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiffs. If any such warranties were made, whether express or implied, which APUS specifically denies, then Plaintiffs failed to give notice of any breach thereof. New York Uniform Commercial Code § 2-607(3).



**SIXTH AFFIRMATIVE DEFENSE**

35. Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code and/or the laws of New York.

**SEVENTH AFFIRMATIVE DEFENSE**

36. Upon information and belief, APUS has no present knowledge of culpable conduct or assumption of risk on the part of the Plaintiffs, which may have caused or contributed to the incident or damages alleged in the complaint, but in order to preserve its defense in the event that it obtains such knowledge, APUS alleges that culpable conduct or assumption of risk on the part of the Plaintiffs caused or contributed to said incident or damages.

**EIGHTH AFFIRMATIVE DEFENSE**

37. Upon information and belief, pursuant to § 4545 and other applicable sections of the New York Civil Practice Law & Rules, APUS is entitled to a set off against the amount of any verdict or any monies collected from a collateral source of payment as set forth in said law.

**NINTH AFFIRMATIVE DEFENSE**

38. Upon information and belief, if APUS is found liable along with one or more co-defendants, it is requested that the relative culpability of the defendants be determined and judgment over be granted in accordance with that determination; in the event APUS is found liable by reason of the act or omission of one or more co-defendants, it is requested that judgment over for full indemnity be granted.

**TENTH AFFIRMATIVE DEFENSE**

39. Upon information and belief, the injuries and damages claimed by Plaintiffs, no injuries or damages being admitted, resulted from an intervening and superseding cause or causes, including but not limited to the actions of other persons and the independent knowledge

and awareness of such other persons of the risks inherent in the use of such product, and any action on the part of APUS was not the proximate or competent producing cause of the alleged injuries and damages.

#### **ELEVENTH AFFIRMATIVE DEFENSE**

40. Protopic® is a prescription medical product. The federal government has preempted the field of law applicable to the design, testing, manufacturing, labeling and warning of prescription medical products. The design, testing, manufacturing, labeling and warning for Protopic® is and was, at all times relevant to this action, in compliance with applicable federal law. Plaintiffs' cause of action against APUS, therefore, fails to state a claim upon which relief can be granted; such claim, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

#### **TWELFTH AFFIRMATIVE DEFENSE**

41. To the extent that Plaintiffs assert that APUS failed to provide an adequate warning to Plaintiffs with respect to the use of the prescription drug Protopic®, APUS states that any obligation to warn was discharged through the provision of an adequate warning to the treating and prescribing physicians, including, but not limited to, information regarding indications, contraindications, warnings, precautions, and adverse reactions. If any injuries were sustained by Plaintiffs as alleged, such injury resulted, in whole or in part, by the failure of Plaintiff and/or her physicians to heed, observe, and follow warnings that were provided and/or other information readily available to Plaintiff and/or her physician.

#### **THIRTEENTH AFFIRMATIVE DEFENSE**

42. Upon information and belief, Plaintiffs' alleged injuries and Plaintiffs' damages, if any, proximately resulted from the misuse, abuse, unintended, or unforeseeable use of

Protopic®, and consequently no act or omission on the part of APUS proximately caused any of Plaintiffs' claimed injuries or damages.

**FOURTEENTH AFFIRMATIVE DEFENSE**

43. Upon information and belief, the injuries or the expenses alleged by Plaintiffs may have been caused, in whole or in part, by an idiosyncratic reaction, operation of nature or act of God, or by pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses.

**FIFTEENTH AFFIRMATIVE DEFENSE**

44. At all relevant times, Protopic® was reasonably safe and reasonably fit for its intended use and accompanied by proper warnings, information, and instructions, pursuant to generally recognize prevailing standards in existence at the time as set forth in the package inserts and literature for Protopic®. Protopic® was not defective or unreasonably dangerous.

**SIXTEENTH AFFIRMATIVE DEFENSE**

45. Upon information and belief, in this instance, APUS states that the benefits of Protopic® outweighed its risks, if any, which may be attendant to its use.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

46. Upon information and belief, Plaintiffs' claims are or may be barred by the doctrines of laches, waiver, estoppel and judicial estoppel.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

47. Protopic® is a prescription medical product that falls within "comment k" and "comment j" exceptions to strict liability, as defined in Restatement (Second) of Torts, § 402A. Protopic® is therefore neither defective nor unreasonably dangerous when properly prepared and accompanied by proper warnings and instructions for use. At all times material to Plaintiffs'

Complaint, Protopic® was properly prepared and accompanied by proper warnings and instructions for use.

**NINETEENTH AFFIRMATIVE DEFENSE**

48. Protopic® is a prescription drug that falls within Restatement Third, Torts: Products Liability § 6. Therefore, Protopic® is reasonably safe in design if a reasonable health care provider would prescribe Protopic® to any class of patients. At all times material to the Complaint, Protopic® was accompanied by reasonable instructions and warnings to the prescribing physician and other health-care providers.

**TWENTIETH AFFIRMATIVE DEFENSE**

49. Plaintiffs' claims may be barred, in whole or in part, due to failure to join indispensable parties and/or to bring claims against the real party in interest.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

50. Plaintiffs' claims are barred by the "state of the art" defense. Protopic®, when placed into the stream of commerce, was a reasonably safe and effective prescription drug in light of the then existing and reasonably available scientific, medical, and technological knowledge. To the extent that Plaintiffs claim that Protopic® was dangerous or defective in certain respects, APUS states that any such risks associated with Protopic® were not known and could not reasonably be discovered at the time the product was placed into the stream of commerce.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

51. Plaintiff has failed to plead allegations of fraud and misrepresentation with particularity as required by Federal Rule of Civil Procedure 9(b) and CPLR § 3106(b).

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

52. Upon information and belief, Plaintiffs have failed to mitigate any alleged damages.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

53. Plaintiffs are barred from recovering any damages because there was no practical or technically feasible design or formulation that would have prevented the harm alleged without substantially impairing the usefulness or intended purpose of the product.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

54. Upon information and belief, the claims alleged in Plaintiffs' Complaint have been improperly joined and should be severed.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

55. Upon information and belief, this Court lacks personal jurisdiction over APUS and the exercise of jurisdiction would not satisfy due process of law.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

56. Upon information and belief, this Court is not the proper venue for this case.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

57. Upon information and belief, a New York forum is inconvenient to the parties, and this matter should be transferred to its appropriate jurisdiction.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

58. Upon information and belief, in the event a verdict or decision is rendered in favor of the Plaintiffs against APUS, APUS is entitled to limitations on liability set forth in Article 16 of the New York Civil Practice Law & Rules

WHEREFORE, APUS demands judgment as follows:

1. Dismissing the Complaint herein, or
2. Reducing Plaintiffs' recovery against APUS according to the limitations of liability as set forth in Article 16 of the CPLR, and
3. Reducing Plaintiffs' recovery in the proportion to which the Plaintiffs' culpable conduct, assumption of risk and want of care bears to the culpable conduct which caused the Plaintiffs' damages, and
4. Such other and further relief as to this Court may seem just proper and equitable, together with the costs and disbursements of this action.

**JURY DEMAND**

APUS demands a trial by jury as to all issues.

Respectfully submitted,

BY:           /s/ Scott R. Jennette          

Sharon M. Porcellio

Scott R. Jennette

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 6th day of March, 2009, a true and correct copy of the foregoing document was served via the Court's electronic notification system upon:

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BROWN CHIARI  
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/s/ Scott R. Jennette  
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